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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,911	08/18/2005	Ib Joergensen	HO-US045220	4306
22919	7590	12/15/2005	EXAMINER	
SHINJYU GLOBAL IP COUNSELORS, LLP 1233 20TH STREET, NW, SUITE 700 WASHINGTON, DC 20036-2680			THANH, LOAN H	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 12/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/511,911

Applicant(s)

JOERGENSEN ET AL.

Examiner

LoAn H. Thanh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☒ Claim(s) 17-20 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 August 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 10/29/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, a second catheter shaft portion (claim 5), a case on the catheter shaft (claim 6), the stent (claim 9), the metal spring bridging (claims 7,8,17-20), the kink protection as a nylon tube coating (claim 11) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Specification***

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: See claims 7-8, 17-20. There is a lack of support in the specification of the metal spring element. See claim 6. There is a lack of support for the case to be arranged on the catheter shaft. There is however a case on the inner pipe 13 at the transition region.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-8, 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 is vague and indefinite because "second catheter shaft portion" makes it unclear what the first catheter shaft portion encompasses.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3,5-6,10,12,14-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Mueller, Jr. ( USPN 4,775,371).

Mueller, Jr. disclose a balloon catheter having 2 pipes 11 and 13 which are coaxial. Mueller, Jr. further discloses a guidewire lumen 14 and an inflation lumen 16. The transitional portion is considered the neck down portion of the relatively stiffer tubular member /kink protection 18. See figures 5-7. Mueller, Jr. discloses the tubular members as low density polyethylene. It is inherent that the proximal end has a connecting piece/hub.

Claims 1-3, 9-10 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Steese-Bradley (US6,544,224).

Steese-Bradley discloses a balloon catheter having catheter shaft 11, a guide wire 15 , a guide wire lumen, an inflation/deflation lumen, and reinforcing pipes/tube 12,13. See figures 1-4.

Claims 1-6,9, 10, 12, 14-15,16 rejected under 35 U.S.C. 102(e) as being anticipated by Wantink ( US 6,746,423).

Wantink discloses a balloon catheter for deploying a stent 16 having a catheter shaft comprising of several tubes . The inflation/deflation lumen 20 and the guidewire lumen 21 is surrounded by reinforcing pipes/tubes. The reinforcing pipe is stainless

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steel 18 or 22. The kink protection is shown at 36 or proximal to it. The concentric pipes are shown in figure 1.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11,13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wantink ( US 6,746,423).in view of Wang et al. (US 5,951,494).

See Wantink above. Wantink discloses a dilatation balloon catheter. However, Wantink is silent to a coating of the surface. Wang discloses coating the metallic inner lumen of guidewire lumens in balloon catheter or catheters in general to provide smooth introduction of the guidewire into the lumen. It would have been obvious to one of ordinary skill in the catheter art at the time the invention was made to modify the balloon catheter of Wantink with a coating as taught by Wang in order to provide smooth, lubricious introduction of a guidewire into the lumen.


### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H. Thanh whose telephone number is (571) 272-4966. The examiner can normally be reached on Mon. - Fri. (First Friday off).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
LoAn H. Thanh  
Primary Examiner  
Art Unit 3763

LT  
12/12/05